1. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT

Heather Tanner
Reliant Technologies, Inc.
260 Sheridan Ave.
Palo Alto, CA 94306
650 473-0200, 103
650 473-0537 fax
htanner@reliant-tech.com

NAME OF DEVICE

Trade Name:	Reliant Laser II System and Accessories (Fraxel SR Laser System)
Common Name:	Laser Surgical Instrument
Regulation Number	878.4810
Product code:	GEX
Device Panel:	General Surgery/Restorative Devices
Device Classification:	Class II

PREDICATE DEVICES

Name: Reliant Laser System II
510(k) #: K040617

Name: Reliant Laser System
510(k) #: K031795

Name: Lumenis UltraPulse Encore
Carbon Dioxide Surgical Laser
and Delivery Device Accessories
510(k) #: K022060

DEVICE DESCRIPTION

The Reliant Laser System II consists of a set of fiber lasers, controlled by an embedded processor, to be used in dermatology. The laser system uses scanning and focusing optics to deliver a pattern of thermal energy to the epidermis and upper dermis. Device accessories include tip attachments and pre-treatment solution.

INDICATION FOR USE STATEMENT

The Reliant Laser System II is intended for use in:

Dermatological procedures requiring the coagulation of soft tissue;

Treatment of periorbital wrinkles;

Photocoagulation of pigmented lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and dyschromia;

Skin resurfacing procedures.

SUBSTANTIAL EQUIVALENCE COMPARISON

Technological Characteristics

There has been no change to the Reliant Technologies Laser System II. The system is identical to the Reliant Technologies 510(k)s cleared under 510(k) K031795 and K040617.

Indications for Use

Substantial equivalence for the Reliant Laser II System is supported by the predicate devices listed in this submission, which have identical or similar indication statements.

Clinical Performance Data

Clinical analysis was conducted on Non-Significant Risk and IDE Reliant studies to support the change in the language in the indications for use statement. Sufficient safety and efficacy data has been gathered to determine that the Reliant Laser II System performs as clinically intended and that no new issues of safety and effectiveness are introduced.

CONCLUSION

Based on the design, materials, function, intended use and clinical evaluation, the Reliant Laser II System and Accessories is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. Safety and effectiveness are reasonably assured, justifying 510(k) clearance. No changes are being made in the laser or accessories. The technical, mechanical, performance, and electrical performance data submitted in the Reliant Technologies cleared 510(k)s are valid, and unaffected by this change in labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2005

Ms. Heather Tanner
Clinical Research/Regulatory Affairs Manager
Reliant Technologies, Inc.
260 Sheridan Avenue, Suite 309
Palo Alto, California 94306

Re: K042319
Trade/Device Name: Reliant Laser System II and Accessories (Fraxel SR Laser System)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 7, 2004
Received: December 10, 2004

Dear Ms. Tanner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N Melkerson

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042319

Device Name: Reliant Laser System II and Accessories (Fraxel SR Laser System)

Indications For Use:

"The Reliant Laser System II is intended for use in:

Dermatological procedures requiring the coagulation of soft tissue;

Treatment of periorbital wrinkles;

Photocoagulation of pigmented lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and dyschromia;

Skin resurfacing procedures."

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042319